

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
LIBERTY MUTUAL INSURANCE COMPANY,
LIBERTY MUTUAL FIRE INSURANCE COMPANY,
LIBERTY INSURANCE CORPORATION, THE FIRST
LIBERTY INSURANCE CORPORATION, LM
INSURANCE CORPORATION, LIBERTY MUTUAL
MID-ATLANTIC INSURANCE COMPANY, LIBERTY
COUNTY MUTUAL INSURANCE COMPANY, LM
PROPERTY and CASUALTY INSURANCE COMPANY,
SAFECO COMPANY OF INDIANA, and AMERICAN
STATES INSURANCE COMPANY,

Docket No.:
17-CV-6313 (ILG)(CLP)

Plaintiffs,

-against-

WOODSIDE CHEMISTS, INC.,
RONIKA SONI, LAM C. QUAN, M.D., LEONID
REYFMAN, M.D., LEONID LITOVSKIY, P.A. ROBERT
B. LANTER, D.O., MAXIM TYORKIN, M.D., PERICLES
S. HADJIYANE, M.D., TIMOTHY CANTY, M.D.,
JAMES A. GRIFFIN, P.A.

Defendants.

-----X

**DEFENDANTS WOODSIDE CHEMISTS, INC., AND RONIKA
SONI'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO DISMISS**

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PRELIMINARY STATEMENT

Defendants Woodside Chemists, Inc. (“Woodside”) and Ronika Soni (“Soni”)¹ submit this memorandum of law in support of their motion to dismiss the Complaint pursuant to FRCP 12(b)(6). Because the Complaint fails to meet the pleading requirements of Rule 9 or *Twombly* the Court should dismiss this action.

The various insurance companies operating under the Liberty Mutual² trade name have alleged that the defendants in this lawsuit have purportedly entered into a fraudulent scheme by which “unregulated” pain creams are being supplied to persons injured in motor vehicle accidents. The Complaint alleges in repetitive and conclusory form that the Pharmacy Defendants entered into a “kickback scheme” with the Health Care Defendants³ whereby the prescribing health care provider were purportedly paid for their script.

Yet nowhere in the forty-six (46) page complaint does Liberty Mutual specifically allege the details of any purported payment. Instead, the Complaint alleges in repetitive and conclusory form that the creams were purportedly formulated in violation of Federal and State regulations governing the compounding of medications.

However, the Complaint does not identify any statute which the Pharmacy Defendants would have violated by dispensing the creams. The third alternate theory which is also repeated multiple times, but without specificity, alleges that the creams are lacking in medical efficacy and that other less costly alternatives should have been dispensed. Again, the Complaint is

¹ Woodside and Soni are also referred to collectively as “Pharmacy Defendants.”

² The Complaint lists the following companies as Plaintiffs in the caption - Liberty Mutual Insurance Company, Liberty Mutual Fire Insurance Company, Liberty Insurance Corporation, The First Liberty Insurance Corporation, LM Insurance Corporation, Liberty Mutual Mid-Atlantic Insurance Company, Liberty County Mutual Insurance Company, LM Property and Casualty Insurance Company, Safeco Company of Indiana, and American States Insurance Company. For ease of reference they are referred to collectively as Plaintiffs and/or Liberty Mutual.

³ The Complaint lists the following practitioners as defendants in the caption – Leonid Reyfman, M.D., Leonid Litovskiy, P.A. Robert B. Lanter, D.O., Maxim Tyorkin, M.D., Pericles S. Hadjiyane, M.D., Timothy Canty, M.D. and James A. Griffin, P.A. As the Complaint does not provide details as to any of these individuals (other than their residences and dates of licensure) or their actions, they are referred to collectively as “Health Care Defendants.”

deficient as it does not identify any particular cream which was dispensed to a particular patient or analyze how the cream was medically unnecessary for that individual.

Simply put, the Complaint does not state fraud claim against the Pharmacy Defendants, due to Liberty Mutual's failure to provide any specifics of the alleged fraud. Indeed, other than the identification of the Pharmacy Defendants, Health Care Defendants and Liberty Mutual itself, the Complaint lacks any specificity as to the alleged fraud. Similarly, the Complaint fails to state a cause of action for unjust enrichment as the Complaint lacks a description of the basic elements of the claim.

Lastly, since the damages of cause of action are defective, it is respectfully submitted that the Court should abstain from hearing the Declaratory Judgment claim.

STATEMENT OF FACTS⁴

The Complaint alleges that Liberty Mutual has filed this lawsuit in order to recover \$20,500 which "the Defendants have wrongfully stolen from Liberty Mutual." (Complaint at ¶1). Additionally, the Complaint indicates that it seeks a declaration that Liberty Mutual is not required to pay an additional \$222,000 in "fraudulent billing" (Complaint at ¶1) which clearly is the motivating factor for the suit, given the economics of the damages claim.

The Complaint further alleges that the Pharmacy Defendants have "billed New York State automobile insurers approximately \$2,000 to in excess of \$6,000 for a single tube" of the allegedly fraudulent pain creams. (Complaint at ¶2). However, at no point does the Complaint identify any specific patient whose "fraudulent" pain cream was paid for by any of the ten (10) Liberty Mutual companies. Additionally, the Complaint never identifies: (1) any specific patient who was provided with a particular pain cream; (2) any specific health care provider who

⁴ As this motion is pursuant to FRCP 12(b)(6) all facts are derived from the Complaint which is presumed by the Court to be true. A copy of the Complaint is appended to the accompanying Harfenist Declaration as Exhibit "A." The Defendants do not admit the truth of the allegations and reference them solely for the instant motion.

prescribed a particular pain cream to a specific patient; (3) any individual patient's symptoms which purportedly could have been treated by a less expensive alternative treatment; (4) any payment purportedly made by Liberty Mutual for the "fraudulent pain cream"; (5) any less expensive alternative treatment which purportedly could have been provided to the unnamed patient; (6) any individual patient's symptoms were allegedly not ameliorated by the "fraudulent" pain cream and (7) the date and amount of any payment that was allegedly made to the health care provider in exchange for the prescription.

Given the fact that the Pharmacy Defendants allegedly billed an average of \$4,000 per tube (based on the allegations in ¶2), there could not be any more than five or six tubes which are the subject of the fraud and unjust enrichment claims, yet the Complaint lacks any specificity as to the most basic of the elements of the claims.

Rather than provide any specifics of the alleged fraudulent scheme, the Complaint alleges generally that after the "scheme began in 2015", the parties engaged in the following activities:

(i) Produced and dispensed the Fraudulent Compounded Pain Creams pursuant to predetermined fraudulent protocols designed solely to financially enrich themselves, based on prescriptions solicited by Woodside Chemists, without regard for the topical efficacy of the compounded pain creams or the availability of a wide range of commercially available, FDA approved medications proven to have therapeutic effects, which are available at a fraction of the cost;

(ii) Participated in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic, medically unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams produced by Woodside in exchange for unlawful kickbacks paid by Woodside Chemists; and

(iii) Woodside Chemists engaged in illegal bulk compounding by producing and exclusively dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on pharmacies, drug manufacturers and outsourcing facilities

(Complaint at ¶6).

The Complaint contains four causes of action which seek declaratory relief and damages against the Pharmacy and Health Care Defendants. The First Cause of Action seeks a declaration that Liberty Mutual should not be required to pay Woodside \$222,000 in pending and previously denied claims because the bills were allegedly the product of one of the three theories of fraud. The Second Cause of Action seeks recovery of \$20,500 under a fraud theory against “all Defendants” based upon the bills and submissions being allegedly improper as the product one of the three theories of fraud. The Third Cause of Action seeks recovery solely as against the Health Care Defendants for aiding and abetting the Pharmacy Defendants’ fraud. The Fourth Cause of Action seeks recovery against “all Defendants” under a theory of unjust enrichment.

POINT I

THE STANDARD OF A MOTION TO DISMISS UNDER FRCP 12(b)(6)

Under the Supreme Court decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), a 12(b)(6) motion examines whether the pleading contains enough facts to render the underlying legal theory plausible. *See generally Ruotolo v. City of New York*, 514 F.3d 484 (2d Cir. 2008) (affirming dismissal of complaint and denial of leave to replead where amended complaint failed to plead “enough facts to state a claim to relief that is plausible on its face” under *Twombly*).

As was later described by the Supreme Court in *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 174 L.Ed.2d 128 (2009) “[t]he plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are “merely consistent with” a defendant's liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’”

In applying the *Iqbal/Twombly* plausibility test, this Court stated in *Forgione v. City of New York*, 2012 WL 4049832, at *3 (E.D.N.Y. Sept. 13, 2012) a “claim is facially plausible when ‘the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’” *See also Sprint Sols., Inc. v. Sam*, 206 F. Supp. 3d 755, 760 (E.D.N.Y. 2016)(“[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss,’ and ‘determining whether a complaint states a plausible claim for relief will ... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense”).

Since the Complaint contains a state law fraud claim, it is subject to FRCP 9(b)’s heightened pleading standards which requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” In meeting this standard, conclusory allegations of fraud are insufficient. *See generally D'Alessandro v. City of New York*, ___ F.3d ___, 2017 WL 4641256, at *4 (2d Cir. Oct. 17, 2017)(“D'Alessandro's complaint contains mere conclusory allegations of fraud...none of which we accept as true”). *See also Eisenstein v. Whitman*, 4 F. App'x 24, 26 (2d Cir. 2001)(“Finally, the district court correctly determined that Eisenstein's allegations of fraud against PSI were wholly conclusory and did not satisfy the heightened pleading requirements for fraud set out in Rule 9(b) of the Federal Rules of Civil Procedure”).

The fraud claim in this case fails FRCP 9(b) in that it does not provide any defendants with fair notice of the claims against them. Although the prolix Complaint alleges the same theories over its forty-six (46) pages, at no point does it actually state with particularity the circumstances constituting fraud. Conspicuously absent are any particulars regarding the alleged kickback scheme. Instead, the complaint merely says it exists. Rather than have a factual basis

for the claim, the plaintiff brazenly made it up hoping somehow to get to discovery and go on a fishing expedition. That should not happen.

POINT II

THE COMPLAINT DOES NOT PROPERLY ALLEGE A KICKBACK SCHEME

As this Court has noted, the pleading requirement of “Rule 9(b) is intended to serve several purposes: to provide a defendant with fair notice of a plaintiff’s claim, to safeguard a defendant’s reputation from improvident charges of wrongdoing, to protect a defendant against the institution of a strike suit, and to discourage the filing of complaints as a pretext for discovery of unknown wrongs.” *Maverick Fund, L.D.C. v. Converse Tech., Inc.*, 801 F. Supp. 2d 41, 53 (E.D.N.Y. 2011). In the instant matter, the Complaint fails all of Rule 9(b)’s intentions as it broadly paints all defendants as being involved in a kickback scheme and tarnishes each defendant’s reputation without ever identifying any specifics of the scheme.

One of the main theories alleged in the Complaint is that Liberty Mutual should be entitled to recover payments made for the “fraudulent pain creams” because they were purportedly a product of a kickback scheme. The allegations of a kickback scheme are repeated on no less than twenty (20) occasions in the Complaint (¶¶3,4,6,54,134-144,162,169,173,180,189), but the Complaint lacks the most basic of details of the alleged kickbacks. Although the Complaint identifies the eight (8) Health Care Defendants by name, the only specific reference to any Health Care Defendant is the paragraph which contains the practitioner’s name and date of licensure in New York.

Similarly, the Complaint lacks description of any payment, and does not even allege when the payments began or even the method of payment. Additionally, the Complaint does not at any point identify the particular patient who received a “fraudulent pain cream” or the

payment which Liberty Mutual purportedly paid and would now like to recover from the Pharmacy Defendants. The bottom line is that the fraud claim based upon “kickbacks” is unsupported by any factual basis and was simply fabricated in order to justify dragging the Health Care Defendants into this case and create a claim that might attract the Court’s attention. Instead, its doomed for dismissal.

When pleading fraud premised on a kickback scheme it is important to actually plead the specifics of the alleged fraud. See generally *Gov’t Employees Ins. Co. v. MLS Med. Grp. LLC*, 2013 WL 6384652, at *10 (D.N.J. Dec. 6, 2013)(“To the extent the fraudulent nature of the bills is based on the allegation that MLS obtained its GEICO-insured patients as a result of a kickback arrangement with referring doctors, the Amended Complaint likewise fails to allege fraudulent billing with any particularity”).

In the matter of *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 399 (S.D.N.Y. 2016), Judge Castel of the Southern District dismissed a similarly deficient complaint on FRCP 9b grounds, noting that “plaintiffs plead that Ponte learned that other employees in her department processed ‘improper inducement payments.’ They do not, however, allege any specific circumstances—from who, when, and in what context—she learned that employees had been making improper inducements payments.” See also *Farberware, Inc. v. Groben*, 764 F. Supp. 296, 303 (S.D.N.Y. 1991)(“[T]his section of the Amended Complaint contains only the allegation that he “and/or” AMC paid kickbacks to Groben. While such actions constitute the type of information that is likely to be particularly within the knowledge of the defendants, this averment, made on information and belief, is insufficient under Rule 9(b)”).

Similarly, in the matter of *In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595 (S.D.N.Y. 2005), Judge Stein of the Southern District dismissed a kickback claim involving JP Morgan Chase and Enron under FRCP 9(b), finding that

The charge that JPM Chase's officers violated Sections 18 U.S.C. 1005, as well as 215, by receiving “kickbacks” in exchange for loans to Enron suffers from the same lack of support in the factual allegations. Plaintiffs claim that the benefit JPM Chase executives obtained was the opportunity to invest in LJM2 and other Enron SPEs that had unusually high rates of return for investors. Nevertheless, there are no particular factual allegations that support the conclusory assertion that these investment opportunities were provided as “kickbacks,” let alone that these opportunities were offered with fraudulent intent.

Id. at 632.

Within the fertile ground of *qui tam* litigation premised upon alleged kickbacks for medical referrals, the Courts have made clear that allegations of kickback schemes lacking in specifics as to payments and motivation fail to properly plead fraud claims under FRCP 9(b). In *U.S. ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 895 F. Supp. 2d 872 (N.D. Ill. 2012) the court dismissed a kickback claims under FRCP 9(b), stating:

The Court finds that Relator has not met the Rule 9(b) specificity requirements with regards to the allegations concerning several fraud categories, including the allegations involving cash and gift kickbacks to physicians, prescription recycling, falsified customer copay records being issued to customers, and the use of another pharmacy's Medicare Supplier Billing Number. In all these categories, no single instance is definitively identified. For instance, in regards to doctor kickbacks, the allegations are that an employee saw prescription reports detailing prescriptions per doctor and that checks that were issued to doctors for those prescriptions (although no specific check or payment is ever identified). There is no linkage of a specified kickback check to a specified prescription or to a specified patient. Nor is a specific check ever linked to a specified doctor (although a group of specified doctors are named), on a specified date, upon order of a specific employee

Id. at 879.

Similarly in *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890 (5th Cir. 2013), the Fifth Circuit affirmed the dismissal of a complaint alleging kickbacks in which the relator

[A]lleges WCCH violated the AKS by inducing physicians to provide improper referrals for lab services. The elements of the AKS violation must also be pleaded with particularity under Rule 9(b), because they are brought as a FCA claim. Nunnally's complaint merely offers sweeping and conclusory allegations of "verbal agreements" between WCCH and "various physicians," without a shred of detail or particularity. We are given no information on the contents of those agreements, the identity of any physicians, actual inducements, or improper referrals. The sole "specificity" in the complaint is an "example" of an agreement to charge physicians \$3.60 for a blood test, while later charging Medicare \$10.60 for the same test. This "example" is insufficient because it does not allege, nor reliably indicate, that the two differing pay scales constitute "remuneration" to the physicians. It does not even indicate that these amounts are real rather than hypothetical. The complaint does not specify who in particular was involved in this "agreement," or how it constituted an illegal kickback.

Id. at 894 (internal citations omitted).

In this case, the Complaint fails FRCP 9(b) as the allegations of kickbacks are pleaded as basic generalized statements that the Health Care Defendants as a class were allegedly paid unspecified kickbacks for referring patients for "fraudulent pain creams." This allegation woefully fails the language and purpose of FRCP 9(b). To prove a claim of fraud based upon a kickback- a serious allegation against a medical professional- the claim must have some particularly as to who made the kickback when it was made how much it roughly was for. As the kickback claim in this case lacks these basic factual elements it must be dismissed.

POINT III

THE COMPLAINT DOES NOT PROPERLY ALLEGE THE SPECIFICS OF THE LACK OF MEDICAL NECESSITY FRAUD CLAIM

Liberty Mutual alternate fraud theory that the Pharmacy Defendants allegedly provided the "fraudulent pain creams" based on prescriptions solicited by Woodside "without regard for the topical efficacy of the compounded pain creams or the availability of a wide range of commercially available, FDA approved medications proven to have therapeutic effects, which are available at a fraction of the cost" grossly fails the most rudimentary pleading requirements of such a claim.

The Complaint alleges that Liberty Mutual detrimentally relied on bills which were submitted for payment by the Pharmacy Defendants because the bills were false and misleading in that they were either the product of a kickback scheme or misrepresented the medical necessity of the “fraudulent pain creams” and/or were manufactured in violation of FDA and/or State compounding regulations. (Complaint at ¶159). As discussed above, the kickback scheme allegations fail the pleading requirements under FRCP 9(b) as they lack the most basic of details as to the alleged kickbacks. Similarly, the fraud theory premised on alleged lack of medical necessity and/or violation of FDA and/or State compounding regulations must be dismissed under FRCP 9(b).

As explained by the Second Circuit in *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) “[t]his Court has read Rule 9(b) to require that a complaint “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent. *See also Nelson v. MillerCoors, LLC*, 246 F. Supp. 3d 666, 672 (E.D.N.Y. 2017)(“Claims premised on fraud must meet Rule 9(b) of the Federal Rules of Civil Procedure’s heightened pleading standard, which requires pleadings to “state with particularity the circumstances constituting the alleged fraud”) *See also In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (“Thus, Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of securities fraud with all of the essential factual background that would accompany ‘the first paragraph of any newspaper story’—that is, the ‘who, what, when, where and how’ of the events at issue”).

Similar to the alleged kickback scheme, Liberty Mutual’s fraud claim premised on the alleged billing fraud by which the Pharmacy Defendants allegedly either misstated: (1) the medical necessity of the pain creams or (2) their compliance with FDA and State law must be

dismissed under FRCP 9(b) as the Complaint lacks specificity in that it does not specify the statements made nor explain how the statements were fraudulent.

A. The Medical Necessity Billing Fraud Claims Fail FRCP 9(b)

Although the Complaint alleges that the Pharmacy Defendants submitted bills for the “fraudulent pain creams”, the Complaint never alleges: (1) any specific patient who was provided with a particular pain cream; (2) the identity of any specific health care provider who prescribed a particular pain cream to a specific patient; (3) the individual patient’s symptoms which purportedly could have been treated by a less expensive alternative treatment; (4) the payment purportedly made by Liberty Mutual for the “fraudulent pain cream”; (5) the less expensive alternative treatment which purportedly could have been provided to the unnamed patient and (6) that the individual patient’s symptoms were allegedly not ameliorated by the “fraudulent” pain cream.

Given the scant number of bills which could potentially have been paid by Liberty Mutual, the failure to plead these elements with particularity justifies dismissal of the fraud claim. Indeed, the Complaint alleges at ¶¶2,58 and 151, that the Pharmacy Defendants allegedly billed “approximately \$2,000.00 to in excess of \$6,000.00 for a single tube”, which would average to \$4,000 per tube. Yet Liberty Mutual has sought recovery of \$20,500, making the claim over no more than five or six tubes.

Nonetheless, the Complaint lacks the most basic of specificity as to the bills which purportedly fraudulently induced Liberty Mutual to pay the Pharmacy Defendants. Furthermore, since the Complaint names ten (10) plaintiff Liberty Mutual Companies and eight (8) Health Care Defendants, it is unlikely, if not impossible that each named Liberty Mutual plaintiff could

have been victimized by this alleged schemer and each Health Care Defendant aided and abetted the injury purportedly sustained by Liberty Mutual. As such, it is respectfully submitted that the fraud claim should be dismissed.

Instead, Liberty Mutual alleges in the most general terms that “patients” were prescribed creams which were allegedly of dubious medicinal value and that less expensive alternatives were available. This clearly does not satisfy the dictates of FRCP 9(b) and justifies dismissal of the fraud claim premised on this theory.

B. The Compounding Fraud Claims Fail FRCP 9(b)

An additional fraud theory alleged by Liberty Mutual is premised upon the Pharmacy Defendants’ misrepresenting that they have complied with Federal and/or State regulations as the Complaint alleges that the Pharmacy Defendants are purportedly “bulk compounding” the “fraudulent pain creams.” This third theory fails as Liberty Mutual has misrepresented the Federal and State regulations governing the compounding of medicines.

Liberty Mutual begins its “Overview of Compounded Drug Products” by stating at ¶44 of the Complaint that:

Pursuant to Section 503A of the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended by the Compounding Quality Act, the laws applicable to drugs regulated by the FDA, including the laws relating to the safe manufacturing of drugs, generally do not apply to a "compounded" drug product: (1) if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order that a compounded product is necessary for the identified patient, and (2) if the compounding is by a licensed pharmacist in a state licensed pharmacy.

(Complaint at ¶44).

The Complaint then spends many paragraphs espousing unattributed proclamations as to the purpose of FDA approval and the role of “traditional pharmacy compounding” which it alleges must be formulated based on an individual prescription under 21 USC 353a. (Complaint

at ¶¶45-49). Lastly, the Complaint attempts to link the Pharmacy Defendants to individuals who have been indicted for kickback schemes which purportedly involved fraudulently compounded creams. (Complaint at ¶¶54-55).⁵

As the allegations in the Complaint are deemed true for the purposes of the instant motion, the Pharmacy Defendants and Woodside are unable to controvert the false allegations such as Woodside not being a neighborhood pharmacy or only existing to provide bulk pain creams when the store truly is a full-service pharmacy located on Woodside Avenue in Queens. However, the allegations as to 21 USC § 353a and regulation of compounding under the FDA are a different matter. As Liberty Mutual is incorrect as a matter of Federal law as to the compounding of the creams, this claim fails.

21 USC §353a provides two different permissible avenues for pharmacy compounding. Under 21 USC §353a(a)(1), a medicine may be compounded for an individual patient upon receipt of a prescription for that patient. However, under 21 USC §353a(a)(2), a medicine may be compounded by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient, when there is an established relationship between the licensed pharmacist and the physician or other licensed practitioner who will write such prescription order. 21 USC §353a(a)(2)(A).

Although the Complaint similarly alleges that the Pharmacy Defendants purportedly compounded the creams “in set formulations, without tailoring the medications to the individual needs of any individual patient” (Complaint at ¶¶2,57) the FDA published guidance for the pharmacy industry in December 2016 which specifically allows for the advance manufacture and

⁵ Although the Complaint cites to indictments in USA v. Kleyman, 1: 14-CR-598-JHR (DE #1); USA v. Cesario, 3:16-CR-060-M (DE # 3, 75) and USA v. Baldizzi, 8:16-CR-271-MSS-AEP (DE #1), each of these indictments involved allegations of kickbacks in exchange for referral for pain creams, but do not contain any allegations that the creams themselves were illegally compounded or not medically indicated.

storage of pain creams. In its “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry” 2016 WL 7972537 (F.D.A.)⁶ the FDA explicitly allowed for anticipatory compounding and explained that:

2. Compounding Before Receipt of a Valid Prescription Order

Sometimes, based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or health care provider when a prescription for an identified individual patient is received. This is known as anticipatory compounding. Section 503A(a)(2) of the FD&C Act provides for compounding by a licensed pharmacist or licensed physician in “limited quantities before the receipt of a valid prescription order for such individual patient” if:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product;
- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.

Anticipatory compounding can be beneficial because larger batch sizes can increase efficiency and reduce the likelihood of human error that is associated with compounding many small batches of a drug product after the receipt of individual prescriptions for the same drug...

Id. at pp.5-6.

Furthermore, the FDA guidance also contained illustrations of permissible anticipatory compounding which would exceed the number of creams which Liberty Mutual alleges that the Pharmacy Defendants have produced. In so doing the FDA guidance document provided:

The following examples illustrate FDA's policy on anticipatory compounding under section 503A(a)(2):

- A compounder regularly receives valid prescription orders from a particular prescriber or prescribers, or for a particular patient or patients, for compounded

⁶ A copy of the FDA guideline document is appended to the accompanying Harfenist Declaration as Exhibit “B”.

drug X. The highest number of units of drug X for which the compounder has received valid patient-specific prescriptions in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of receiving prescriptions for the drug, and holding no more than that amount to fill new valid patient-specific prescriptions as the compounder receives them, would be consistent with this policy.

- A compounder regularly receives valid prescription orders from a particular prescriber or prescribers, or for a particular patient or patients, for compounded drug X. As of August 1, 2016, the highest number of units of drug X for which the compounder has received such valid patient-specific prescriptions in a 30-day period between August 1, 2015, and August 1, 2016, is 500 units, which were received between July 1, 2016, and July 30, 2016. Based on this 30-day reference period, the compounder produces 500 units of drug X in advance of receiving prescriptions for the drug, and holds no more than that amount to fill new patient-specific prescriptions as the compounder receives them. However, between July 15, 2016, and August 15, 2016, the compounder receives valid patient-specific prescriptions for 750 units of compounded drug X. Therefore, based on this new reference period, on August 16, 2016, the compounder produces up to 750 units of drug X in advance of receiving prescriptions for the drug, and holds no more than that amount to fill new valid patient-specific prescriptions as the compounder receives them. This would be consistent with FDA's policy on anticipatory compounding.

Id. at p.8

Plaintiff's claims regarding the propriety of Woodside's compounding are simply contradictory to the statutory scheme. While the Pharmacy Defendants dispute the allegations as to the character and activities of Woodside as it is a neighborhood pharmacy the Complaint's allegations of compounding show that Woodside would be permitted under 21 USC 353a and the FDA's related guidance to engage in the conduct that Plaintiff's claims was fraudulent. Accordingly, this claim must be dismissed.

POINT IV

THE UNJUST ENRICHMENT CLAIM MUST BE DISMISSED

In order to state a cause of action for unjust enrichment under New York law, a plaintiff must assert that (1) that the defendant was enriched; (2) that the enrichment was at the plaintiff's expense; and (3) that the circumstances are such that in equity and good conscience the defendant should return the money or property to the plaintiff. *Golden Pacific Bancorp v. F.D.I.C.*, 273 F.3d 509, 519 (2nd Cir. 2001). *See also Lake Minnewaska Mountain Houses Inc. v. Rekis*, 259 A.D.2d 797, 686 N.Y.S. 2d 186 (3rd Dept. 1999) and *Wiener v. Lazard Freres & Co.*, 241 A.D.2d 114, 672 N.Y.S.2d 8 (1st Dept. 1998).

As perhaps an afterthought, the final cause of action alleged in the Complaint seeks recovery for alleged unjust enrichment, however the Complaint makes little effort to develop the claim. The cause of action contains six paragraphs, most of which reiterate allegations contained in the prior forty-three pages of the Complaint. In explaining the basis for seeking the equitable relief of return of the \$20,500 which the Complaint alleges was paid by Liberty Mutual to Woodside, the Complaint alleges at ¶189:

The Defendants have been enriched at Liberty Mutual's expense by Liberty Mutual's payments, which constituted a benefit that Defendants voluntarily accepted and profited from, as a result of, among other things, the payments received and the receipt of kickback payments, notwithstanding their improper, unlawful, and unjust fraudulent billing scheme.
(Complaint at ¶189).

Although this cause of action is pleaded as unjust enrichment, it is clearly just a fraud cause of action which is masquerading as an unjust enrichment claim. Indeed, the sole paragraph which discusses the basis for the alleged recovery indicates that it is premised upon the alleged “kickback payments” and “unjust fraudulent billing scheme.” Since this theory is the essence of the fraud claim, Liberty Mutual may not escape the requirements of FRCP 9(b) by calling it

unjust enrichment. *See generally Innovative Custom Brands, Inc. v. Minor*, 2016 WL 308805, at *4 (S.D.N.Y. Jan. 25, 2016) (“If an unjust enrichment claim is “premised on fraudulent conduct,” it is subject to Rule 9(b)’s particularity requirement”).

Lastly, even assuming that the Court were to consider the claim as a non-fraud cause of action it would still fail under *Twombly* as the allegations of a kickback scheme fail to provide factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *See generally Forgione v. City of New York*, 2012 WL 4049832, at *3 (E.D.N.Y. Sept. 13, 2012).

POINT V

THE COURT SHOULD ABSTAIN FROM HEARING THE DECLARATORY JUDGMENT CLAIM

In addition to the deficient fraud and unjust enrichment claims, the Complaint also contains a declaratory judgment claim whereby Liberty Mutual seeks a declaration that it is not required to pay \$222,000 in pending and denied claims. Because a large number of these claims are subject to pending arbitration and litigation, the Court should abstain from hearing the declaratory judgment claim under the *Wilton/Brillhart* abstention.

As noted by the Second Circuit in *Travelers Ins. Co. v. Carpenter*, 411 F.3d 323, 338 (2d Cir.2005), the *Brillhart* doctrine allows a district court in its discretion to abstain from rendering a declaratory judgment when ““the questions in controversy between the parties to the federal suit ... can better be settled in the proceeding pending in the state court.”” The Second Circuit has limited the doctrine is unavailable when a complaint seeks both damages and declaratory relief. *See generally Village of Westfield v. Welch's*, 170 F.3d 116, n. 5 (2d Cir.1999) (“We note that the Supreme Court held in *Wilton v. Seven Falls Co.*, 515 U.S. 277, 115 S.Ct. 2137, 132 L.Ed.2d 214

(1995), that a discretionary standard, and not the *Colorado River* exceptional circumstances standard, governs a district court's decision to stay a declaratory judgment action on grounds of a parallel state court proceeding. *Wilton* does not apply here ... [as] the federal action did not seek purely declaratory relief.”).

In one of the first trial court decisions to apply *Wilton*, this Court explained in *Cadle Co. v. Bankers Fed. Sav. FSB*, 929 F. Supp. 636 (E.D.N.Y. 1996):

In particular, the Court has held that the unique discretionary authority granted to the district courts by virtue of the Declaratory Judgment Act, 28 U.S.C. § 2201, renders the application of the abstention doctrine to suits brought under that Act appropriate. Thus, in suits brought under the Declaratory Judgment Act, “considerations of practicality and wise judicial administration” take precedence over the otherwise prevailing doctrine that federal courts should adjudicate claims within their jurisdiction.

Id. at 638-639 (internal citations and quotations omitted).

In the instant controversy, Woodside has commenced arbitration proceedings before the American Arbitration Association and collections lawsuits in New York State Court, all of which by necessity implicate the same issues in the declaratory judgment claim.⁷ As such, should the Court grant the dismissal of the deficient fraud and unjust enrichment claims, it is respectfully submitted that the Court should abstain from hearing the declaratory judgment cause of action.

⁷ A chart which lists the pending arbitration and litigation proceedings is appended to the accompanying Harfenist Declaration Harfenist Declaration as Exhibit “C”.

CONCLUSION

Considering the foregoing, Defendants' motion should be granted in its entirety.

Dated: Lake Success, New York
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